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09/781,046	02/08/2001	Kangsheng Wang	258/193	9275

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EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,046

Applicant(s)

WANG, KANGSHENG

Examiner

Thaia N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-26 are pending. Claims 22-26 are under current examination.

Election/Restrictions

Claims 1-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group(s), there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Applicant's election without traverse of Group IV [Claims 22-26] in Paper No. 6 is acknowledged.

Specification

The disclosure is objected to because of the following informalities:

p. 2, line 4 begins with a '.

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See p. 2, line 7.

Appropriate correction is required.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 67-71 of copending Application No. 09/537,861. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to sperm specific antibodies. The claims of the '861 Application are broader in scope than instant claims, however the instant claims are a species of the '861 claims as evidenced by claim 70, directed to a sperm-specific antibody. As such, the species claimed in the instant application are made obvious by the '861 Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention consists of an antibody characterized by having binding affinity to a sperm cell. The specification teaches that the linker antibody, mAbC, binds to sperm cells from human, mouse, pig, cow, chicken, goat and sheep [see p. 9, Example II]. The specification further teaches that mAbC was used as the linker antibody to produce transgenic mice and transgenic pigs [see Example VII]. As mAbC is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the antibody smAbC is not so obtainable or available, the requirements of 35 U.S.C. 112, regarding "how to make" may be satisfied by a deposit of the antibody linker. The specification does not disclose a repeatable process to obtain the antibody linker and it is not apparent if it is readily available to the public. If the deposits is to be made under the terms of the Budapest Treaty, then an affidavit or

declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific antibody has been deposited under the Budapest Treaty and that the antibody will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement.

It the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
 - (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
 - (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request of for the effective life of the patent, whichever is longer; and,
 - (d) a test of viability of the biological material at the time of deposit (see 37 CFR 1.807);
- and,
- (e) the deposit will be replaced if it should ever become inviable.

Once the deposit has been perfected, claims 22-26 will be limited the antibody linker mAbC which is characterized by having binding affinity to sperm cells from a plurality of species of animals, wherein a sperm cell bound with the antibody linker mAbC retains the ability to fertilize an oocyte.

The claimed invention is directed to an antibody characterized by having binding affinity to a sperm cell and wherein a sperm cell bound with the antibody retains the ability to fertilize an oocyte. In further embodiments, the sperm cell is a human sperm, mouse sperm, cow sperm, pig sperm, chicken sperm, sheep sperm, and goat sperm, and the antibody also exhibits binding properties to a polynucleotide such that upon fertilization, the polynucleotide is introduced into the zygote.

The specification teaches that the linker antibody, mAbC, has the ability to bind human, mouse and pig sperm cells. In particular, when the human, mouse or pig sperm cells were incubated with different primary monoclonal antibodies, washed, and further incubated with a secondary antibody and FACS sorted, it was found that mAbC bound to the human, mouse, or pig sperm cells. The specification teaches that additionally, mAbC binds to the sperm cells of cow, chicken, goat and sheep [see p. 9 and Figures 2-4]. The specification teaches that mAbC binds specifically to certain antigens expressed in the outer surface of certain human, mouse and pig sperm cells and that the shifts in fluorescence peaks demonstrate

the affinity of mAbC antibody to bind these particular sperm cells. The specification further teaches that the claimed antibody can be used as a linker between human sperm cells and any DNA molecule in *in vitro* fertilization techniques to produce transgenic embryonic stem [ES] cell lines, which can then be induced into various cell types [see Examples III-IV]. The specification further teaches that transgenic mice and pigs were generated using a vector containing the antibody linker mAbC [see Example VII].

It is well-known that the state of the art of antibodies directed to sperm is such that one of skill in the art would expect such antibodies to inhibit fertilization. For example, Yan *et al.* [Int. J. Fert., 31 :77-85, 1986] teach the characterization of a monoclonal antibody that is capable of inducing tail-to-tail agglutination of human sperm [see *Abstract*] and state that human infertility may result from the production of antibodies directed against spermatozoa [see p. 77, 1st paragraph]. Further, Nakamura *et al.* [Biochem. Biophys. Res. Comm., 205:1503-1509, 1994] teach the generation of a monoclonal autoantibody to mouse sperm which reacted exclusively to mouse and rat live sperm tail. Nakamura *et al.* teach that, "It is believed that antisperm antibodies cause infertility in some male and female patients." [See p. 1503, 1st paragraph]. It was found that this mouse sperm autoantibody affected *in vitro* fertilization by a 40% reduction [see pp. 1505-1506, bridging paragraph]. Further, Naz *et al.* teach antibodies to sperm-specific human FA-1 which inhibited *in vitro* fertilization in rhesus monkeys. In particular, Naz *et*

al. teach that the ant-FA-1 monoclonal antibodies reacted with postacrosomal, mid-piece and tail regions of rhesus monkey sperm, as well as human sperm, and that when these antibodies were present in an insemination mixture, inhibited the *in vitro* fertilization of monkey oocytes [see *Abstract* and p. 118-119, bridging paragraph]. Further Naz *et al.* teach that sperm-specific antibodies are being currently investigated for use as a contraceptive vaccine [see p. 112, 1st paragraph and p. 119, *Discussion*]. Kim *et al.* [Biol. of Reprod., 60:1285-1291, 1999] teach antisperm antibodies generated in Hostein bulls by auto-immunization of the bulls with sperm. Bull sperm was then incubated with serum from the immunized and control bulls and it was found that the sperm incubated with the serum of the immunized bulls reduced *in vitro* fertilization rates [see *Abstract*, and *Discussion*].

Accordingly, when taken with state of the art of sperm-specific antibodies, with particular regard to the inhibition of fertilization, it would have required undue experimentation for one skilled in the art to expect that the sperm-specific antibodies of the instant invention would retain the ability to fertilize an oocyte.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites, "a sperm cell bound antibody retains the ability to fertilize an oocyte". It is unclear what the term "sperm bound antibody" encompasses. It is suggested that the claim recite, "a sperm cell bound with the antibody". Claims 23-26 depend from claim 22.

Claim 24, as written, is unclear. The claim recites "cow sperm cell" in line 2 of the claim. The term "cow" is unclear in this claim, because cow typically refers to a female member of species such as cattle, buffalo and elephant. As such, it would not be expected that a cow would have sperm.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)872-9306.



DEBORAH CROUCH
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TNT

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